IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES BEFORE JUDGE GOODWIN:

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Donald R. Ostergard, M.D.)

Pending in *In re C. R. Bard, Inc.*, *2:10-md-2187*, MDL 2187, is the *Daubert* Motion to Exclude or Limit Certain Opinions and Testimony of Dr. Donald R. Ostergard, M.D. [ECF No. 4802] filed by defendant C. R. Bard, Inc. ("Bard"). The motion is now ripe for consideration because the briefing is complete. As set forth below, Bard's motion is **GRANTED in part** and **DENIED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 16,000 cases currently pending, approximately 1,500 of which are in the Bard MDL, 2187 MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara

J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, a docket control order subjects each case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 236 (establishing Wave 4); PTO # 244 (establishing Wave 5). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure for cases designated in Wave 4 and Wave 5. The court instructed the parties to file briefing on general causation issues in the main MDL, MDL 2187, while specific causation *Daubert* motions, responses, and replies were to be filed in the individual member cases. To the extent that an expert is both a general and specific causation expert, the court advised the parties that they could file a general causation motion in the main MDL and a specific causation motion in an individual member case. *See* PTO # 236, at 4; PTO # 244, at 4.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and

(1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods," which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court's role as gatekeeper is an important one. "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness"

> standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Dr. Ostergard is a board-certified obstetrician and gynecologist and former professor of Obstetrics and Gynecology at the University of California, Irvine. He has published hundreds of peer-reviewed articles on the topic of urogynecology and has performed thousands of pelvic surgeries.

A. Bard's Knowledge or State of Mind

First, Bard argues that I should preclude Dr. Ostergard from testifying as to Bard's knowledge or state of mind. I agree; experts may not testify about what other parties did or did not know. However, to the extent Bard seeks to exclude Dr. Ostergard's testimony about factual issues or the knowledge of the medical community in general, I disagree. Expert witnesses may properly offer opinions on these topics. Therefore, Bard's motion is **GRANTED** to the extent that it seeks to exclude evidence regarding Bard's knowledge or intent.

B. FDA Regulatory Requirements and Product Labeling

Second, Bard objects to Dr. Ostergard's opinions about "the purpose of FDA labeling requirements and the ways in which Bard allegedly failed to fulfill those requirements." Bard's Mem. in Supp. of Mot. to Exclude or Limit Certain Ops. & Test. of Donald Ostergard, M.D. ("Bard's Mem. in Supp."), at 8 [ECF No. 4803]. In Bard's view, Dr. Ostergard lacks the qualifications necessary under *Daubert*, to render these opinions, given that his only experience with product labeling is his "review" of

numerous Instructions for Use ("IFU") for mesh products. In response, the plaintiffs concede that they will not offer Dr. Ostergard as an expert on the regulatory requirements for product labels and warnings. Instead, they offer Dr. Ostergard to opine on the risks and adverse reactions that he observed, which were absent from the IFU for Bard's products. The plaintiffs claim that Dr. Ostergard is qualified to offer this opinion.

I agree with the plaintiffs. While I have found Dr. Ostergard unqualified to opine on FDA regulations and whether a product label satisfies those regulations, *see Tyree, et al. v. Bos. Sci. Corp.*, No. 2:12-cv-08633, 2014 WL 5320566, at *36–37 (S.D. W. Va. Oct. 17, 2014), the plaintiffs have confirmed that Dr. Ostergard will not testify on these topics. Rather, as indicated by his expert report, Dr. Ostergard will testify about the risks he perceives that the Avaulta poses to patients, and he will opine that the Avaulta IFU did not convey these risks. A urogynecologist like Dr. Ostergard is qualified to make this comparison. *See, e.g.*, *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362264, at *34 (S.D. W. Va. July 8, 2014) (finding Dr. Blaivas, a urologist, qualified to testify about the risks of implanting a product and whether those risks were adequately expressed on the product's IFU); *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings . . . ." (brackets and internal quotation marks omitted)). Relying on the plaintiffs' assurance that Dr. Ostergard's testimony will be

limited to an evaluation of Bard's warnings based on his knowledge of and clinical experience with the risks of pelvic mesh products—and not on FDA requirements or regulations—Bard's motion on this point is **DENIED as moot**.

C. Properties of Polypropylene

Third, Bard seeks to exclude Dr. Ostergard's opinions regarding properties of polypropylene on the bases that he is unqualified to give them, they lack a reliable basis, and they do not fit with this case. Specifically, Bard seeks to exclude Dr. Ostergard's opinions regarding the impurity, degradation, toxicity, shrinkage, bacteria, and carcinogenicity of polypropylene.

I can dispose of Bard's argument regarding Dr. Ostergard's qualifications by referring to my previous ruling on this matter:

> It is difficult to deride Dr. Ostergard's qualifications generally. He has performed thousands of pelvic organ prolapse surgeries. He has used a variety of synthetic and biologic materials in pelvic reconstruction, including polypropylene mesh. He has extracted polypropylene mesh products from patients. He has treated them for mesh-related complications. He also performed preliminary theoretical work on a new pelvic mesh device for American Medical Systems. Dr. Ostergard has conducted scanning electron microscope imaging of mesh. He is also participating in an on-going study of its degradation characteristics in conjunction with his University of Louisville colleagues. Finally, Dr. Ostergard has published, in a peer reviewed setting, on a variety of synthetic and natural materials used in pelvic reconstruction surgery dating back to the 1980s. I conclude that Dr. Ostergard's qualifications are sufficient to testify about polypropylene.

Tyree, 2014 WL 5320566, at *35–36. I **ADOPT** this ruling here. Bard's motion is **DENIED** on this point.

With respect to reliability and fit, Bard raises several very specific challenges to Dr. Ostergard's opinions on the characteristics of polypropylene. I have addressed these objections before and concluded that Dr. Ostergard's reliance on the research and peer-reviewed work of others, when considered alongside his own peer-reviewed research, satisfied the reliability requirements of *Daubert*. *See id.*; *see also Jones v. C. R. Bard, Inc.*, No. 2:11-cv-00114, at 7–8 [ECF No. 391]. I do not find Dr. Ostergard's report in this case materially different from these prior cases—his opinions continue to arise from the peer-reviewed research of others, in addition to his own research, and his own experience and training as an urogynecologist. Given that Dr. Ostergard's opinions rest upon "good grounds, based on what is known," *Daubert*, 509 U.S. at 590, they must be "tested by the adversary process." *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998). That is, to the extent that Bard finds Dr. Ostergard's opinions to be generalized incorrectly or otherwise lacking, it may attack them via cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). For these reasons, I **FIND** that Dr. Ostergard's opinions regarding polypropylene are sufficiently reliable. Bard's motion is **DENIED** on this point.

My finding of reliability does not apply, however, to Dr. Ostergard's opinions regarding the alleged carcinogenicity of polypropylene. In his expert reports, Dr. Ostergard opines that polypropylene causes cancer when implanted in laboratory

animals. The plaintiffs concede, "Dr. Ostergard does not intend to offer opinions that polypropylene has caused any particular Plaintiff to develop cancer." Pls.' Resp. in Opp'n to Bard's Mot. to Exclude or Limit Certain General Ops. & Test. of Donald Ostergard, M.D., at 7 [ECF No. 4926]. Because Dr. Ostergard cannot draw a connection between the alleged carcinogenicity of polypropylene and any particular plaintiff, I **FIND** that all of his opinions regarding the alleged carcinogenicity of polypropylene, including his opinion that polypropylene causes cancer in animals, do not fit this case. Therefore, Dr. Ostergard's opinions on the alleged carcinogenicity of polypropylene are **EXCLUDED**. Bard's motion is **GRANTED** on this point.

D. Product Design

Fourth, Bard argues that Dr. Ostergard is not qualified to opine on the alleged shortcomings of the design of Bard's Avaulta and Align products because he "has no meaningful experience in product design." Bard's Mem. in Supp., at 16. I disagree. Dr. Ostergard's education, training, and experience encompass all areas of pelvic anatomy and pelvic reconstruction surgery. Moreover, Dr. Ostergard has previously served as an expert witness in a pelvic mesh trial involving the Avaulta Plus. In *Scott v. C. R. Bard, Inc.*, Dr. Ostergard testified as to the deficiencies in the Avaulta Plus, and on appeal, the court found his testimony as determinative in upholding the plaintiff's negligent design claim. *See* 231 Cal. App. 4th 763, 779 (2014) (concluding that although Dr. Ostergard had never implanted the Avaulta Plus, "he was familiar with the design of various transvaginal mesh kits and was an expert in the field of urogynecology," and from his testimony, "the jury could decide whether Bard acted

as a reasonably careful medical device manufacturer when it designed Avaulta Plus"). The state court's admission of Dr. Ostergard as an expert on the Avaulta Plus product reinforces his qualifications. *See, e.g.*, *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 785 (4th Cir. 1998) (affirming the admission of the expert testimony based, in part, on the fact that the expert's opinion "ha[d] been admitted by at least one other district court"). For these reasons, I **FIND** that Dr. Ostergard is qualified to testify about the design of the Avaulta. Bard's motion is **DENIED** on this point.

E. Previously Disclaimed Opinions

Finally, Bard seeks to exclude certain opinions that Dr. Ostergard agreed not to offer during his deposition testimony. The opinions that Dr. Ostergard previously disclaimed are that (1) the insertion procedure for the Align promotes sawing of tissue; (ii) Bard knew of the allegedly rough edges of the Align mesh arms; (iii) polyester mesh is superior to polypropylene mesh for use in sling products; and (iv) the risks and potential complications of treatment with the Align are not any different than those with any other mid-urethral sling. In response, plaintiffs concede that they do not intend to have Dr. Ostergard contradict his deposition testimony, where these opinions were disclaimed. Therefore, Bard's motion on this point is **DENIED as moot**.

IV. Conclusion

To summarize, Bard's *Daubert* Motion to Exclude or Limit Certain Opinions and Testimony of Dr. Donald R. Ostergard, M.D. [ECF No. 4802] is **GRANTED in part** and **DENIED in part** consistent with my reasoning above.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:10-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: September 4, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

CIVIL ACTION NUMBER	Case Name
2:14-cv-03439	Kitchen v. C. R. Bard, Inc. et al.
2:14-cv-18890	McManus v. C. R. Bard, Inc. et al.
2:14-cv-21874	McCray v. C. R. Bard, Inc. et al.
2:14-cv-23401	Barber v. C. R. Bard, Inc. et al.
2:14-cv-28943	Smith et al. v. C. R. Bard, Inc. et al.
2:16-cv-01855	Eiffler v. Sofradim Production SAS et al.